DEPARTMENT OF FOOD AND AGRICULTURE

MILK AND DAIRY FOOD SAFETY BRANCH

PROPOSED REGULATIONS

PERSONAL LICENSES: FLUID MILK COMPOSITION TESTING METHODS

The Department of Food and Agriculture, Milk and Dairy Food Safety Branch, is proposing changes to Articles 13, 14, 14.5, 14.6, 14.7, 14.8 and 21 of Chapter 1, Division 2 of Title 3 of the California Code of Regulations as follows:

1) Repeal section 499.5, 503, 506 and 508; Amend sections 498, 499, 500, 501, 502, 504 and 505; Add section 499.5 of Article 13 of Chapter 1, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Article 13. Personal Licenses and Examinations and Licenses

Section 498. Pasteurizer's Examination and License.

- (a) Any person desiring to obtain a pasteurizer's license as required by <u>Ssection</u> 35168 of the Food and Agricultural Code shall <u>comply with all of the following</u> requirements:
- (1) file an application in writing on appropriate forms supplied by the Department of Food and Agriculture of the State of California File an application with the Department on the Pasteurizer's License Application, Form No. 72-255 (Rev. 7/05), which is incorporated by reference, accompanied by the applicable fee for the license pursuant to Food and Agricultural Code section 35231. The fee is non-refundable and covers Departmental costs of administering the examination.
- (2) Before such license is issued, each applicant must pass a satisfactory written examination and secure a grade of at least 75 percent and demonstrate his ability Obtain a grade of at least 80 percent on a written examination, and obtain a grade of at least 80 percent on an oral and practical examination to demonstrate the ability of the applicant to properly pasteurize milk or its products.
- (b) Each licensed pasteurizer shall keep their current license displayed at all times at the facility where they are employed.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 35161, 35162, 35163, 35164, 35166, 35167, 35168, 35170, 35171 and 35231, Food and Agricultural Code.

Section 499. Milk and Cream Tester's Examination and License.

- (a) Any person desiring to secure a milk and cream obtain a tester's license as required by Section 35161 of the Food and Agricultural Code shall comply with all of the following requirements:
- (1) first file with the Department of Food and Agriculture an application in writing, on an appropriate form provided for the purpose by the said Department File an application with the Department on the Tester's License Application, Form No. 72-202 (Rev. 11/05), which is incorporated by reference, accompanied by the applicable fee for the license pursuant to Food and Agricultural Code section 35231. The fee is non-refundable and covers Departmental costs of administering the examination. Each applicant shall specify the milk and cream testing method intended to be used and for which the license is desired.
- (2) Before any such "license" is issued, the applicant shall be required to pass a satisfactory written examination, securing a grade of at least 70 percent, and an oral laboratory examination and demonstration of technique sufficiently thorough to indicate the ability of the applicant to take accurately, individual and composite samples and to conduct accurate tests on milk and cream and secure a grade of at least 80 percent. Obtain a grade of at least 80 percent on a written examination, and obtain a grade of at least 80 percent on an oral and practical examination to demonstrate the ability of the applicant to conduct accurate tests on milk and cream. The examination shall be adapted to the particular method of testing specified in the application.
- (b) The license, if issued, shall specify the method to be used by the licensee (i.e. Babcock, Mojonnier, InfraRed, Direct Forced Air Oven Drying, etc.) and shall not be construed to permit tests to be made by the applicant using any other method than that specified in the license. Testers may be licensed to perform each of the official final action methods of analysis listed in section 32921 of the Food and Agricultural Code and/or approved testing methods of comparable accuracy listed in section 511.

- (c) A licensed tester shall at all times comply with all laws, rules, and regulations governing the testing of milk or cream purchased, received, or sold on the basis of the compositional components contained therein by any method or process, and must secure accurate results.
- (d) Each licensed tester shall keep their current license displayed at the facility where they are employed.

NOTE: Authority cited: Section 35161 407, Food and Agricultural Code. Reference: Sections 32921, 34261.5, 35161, 35162, 35163, 35164, 35166, 35167, 35168, 35170, 35171 and 35231, Food and Agricultural Code.

Section 499.5. Nonfat Milk Solids Tester's License.

An applicant desiring to secure a nonfat milk solids tester's license as required by Section 35169 of the Food and Agricultural Code shall file with the Department of Food and Agriculture an application on an appropriate form provided by the department. Each applicant shall specify the method intended to be used and for which a license is desired. Before any such license is issued, the applicant shall be required to pass a satisfactory written examination specified by the director, securing a grade of at least 70 percent, and an oral and laboratory examination and demonstration of technique sufficiently thorough to indicate the ability of the applicant to take accurately, individual and composite samples and to conduct accurate nonfat milk solids tests on milk, and to secure a grade of at least 80 percent. The examination shall be adapted to the particular method of testing specified on the application. The license shall specify the method to be used by the licensee and shall not be construed to permit tests to be made by the licensee using any other method than that specified in the license. A nonfat milk solids tester's license will be issued only to the holder of a valid milk tester's license.

NOTE: Authority cited: Section 35169, Food and Agricultural Code.

Section 499.5 Butter Grader's Examination and License.

- (a) Any person desiring to obtain a butter grader's license as required by section 35134 of the Food and Agricultural Code shall comply with all of the following requirements:
- (1) File an application with the Department on the Butter Grader's License Application, Form No. 72-267 (Est. 7/05), which is incorporated by reference, accompanied by the applicable fee for the license pursuant to Food and Agricultural Code section 35231. The fee is non-refundable and covers Departmental costs of administering the examination.
- (2) Obtain a grade of at least 80 percent on a written examination, and obtain a grade of at least 80 percent on an oral and practical examination to demonstrate the ability of the applicant to properly grade butter.
- (b) Each licensed butter grader shall keep their current license displayed at all times at the facility where they are employed.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921, 35134, 35135, 35161, 35162, 35163, 35164, 35166, 35167, 35168, 35171 and 351231, Food and Agricultural Code.

Section 500. Sampler's and Weigher's Examination and License.

- (a) The Department shall issue a general and limited sampler's and weigher's license. The general license shall apply to persons who collect milk samples for basis for payment under section 35163 of the Food and Agricultural Code. The limited license shall apply to processing plant personnel who only collect samples of bulk raw milk for drug residue testing prior to processing under section 32761.5 of the Food and Agricultural Code.
- (b) Any person desiring to secure a license to weigh, or sample milk, or cream, or both, obtain a sampler's and weigher's license as required by Section 35163 of the Food and Agricultural Code shall or section 576.1(c) of Title 3 of the California Code of Regulations shall comply with all of the following requirements:
- (1) first make application in writing on an appropriate form supplied by the Department of Food and Agriculture of the State of California and shall at the same time

pay the original fee of one dollar. File an application with the Department on the Sampler's and Weigher's License Application, Form No. 72-246 (Rev. 2/06), which is incorporated by reference, accompanied by the applicable fee for the license pursuant to Food and Agricultural Code section 35231. The fee is non-refundable and covers Departmental costs of administering the examination.

- (2) Before any such sampler's and weigher's license is issued, the applicant shall be required to obtain a grade of at least 70 percent on a written examination. Before any such license is issued, the applicant shall also obtain a passing grade of 70 percent on an examination demonstrating his ability to take correctly, individual and composite samples and his ability to make correct weights on milk and cream. He shall also prove himself capable of answering intelligently any questions pertaining to his work as a sampler and weigher of milk and cream and Obtain a grade of at least 80 percent on a written examination specific to the type of license to be issued.
- (3) A general sampler's and weigher's license applicant must, in addition to subsections (b)(1) and (2) above, obtain a grade of at least 80 percent on an oral and practical examination to demonstrate the ability of the applicant to correctly collect representative samples, make correct weights on milk and cream and demonstrate the legibility of his writing and figures by properly completing properly and legibly complete a satisfactory form of weigh sheet. A weigh sheet which shall contain the five necessary essentials that must appear on a weigh sheet, namely all of the following essential information: full date on which the milk and cream was received; name and address of person purchasing, receiving, or selling the product weighed; name or number of the patron; net weight of the milk or cream of the delivery or shipment; and the full name and sampler's and weigher's license number of the licensed tester or licensed sampler and weigher person who does the weighing.
- (4) A limited sampler's and weigher's license applicant must, in addition to subsections (b)(1) and (2) above, obtain a grade of at least 80 percent on an oral and practical examination to demonstrate the ability of the applicant to correctly collect representative samples from a bulk milk tanker.
- (c) Each general licensed sampler and weigher shall keep their current license on their person and available for inspection at all times during their work as a licensee.

(d) Each limited licensed sampler and weigher shall keep their current license displayed at all times at the facility where they are employed.

NOTE: Authority cited: Section 35163 407, Food and Agricultural Code. Reference: Sections 32921, 35161, 35162, 35163, 35164, 35166, 35167, 35168, 35170, 35171 and 35231, Food and Agricultural Code.

Section 501. Technician's Examination and License.

- (a) Any person desiring to secure a license to make bacteriological determinations upon milk or cream which determinations are to be used as a basis of for payment or for determining value as required by Section 35167 of the Food and Agricultural Code, shall comply with the following requirements:
- (1) first make application in writing on an appropriate form supplied by the Department of Food and Agriculture of the State of California. File an application with the Department on the Technician's License Application, Form No. 72-252 (Rev. 7/05), which is incorporated by reference, accompanied by the applicable fee for the license pursuant to Food and Agricultural Code section 35231. The fee is non-refundable and covers Departmental costs of administering the examination.
- (2) Before a technician's license is issued to such applicant he shall be required to pass a written, oral and laboratory examination and demonstration of technique sufficiently thorough to indicate the ability of the applicant in making bacteriological determinations on milk and cream which are reasonably accurate, and secure in each of these examinations a grade of at least 70 percent. Obtain a grade of at least 80 percent on a written examination, and obtain a grade of at least 80 percent on an oral and practical examination to demonstrate the ability of the applicant to conduct accurate bacterial determinations on milk and cream.
- (b) Each licensed technician shall keep their current license displayed at all times at the facility where they are employed.

NOTE: Authority cited: Section 35167 407, Food and Agricultural Code. Reference: Sections 32921, 35161, 35162, 35163, 35164, 35166, 35167, 35168, 35170, 35171 and 35231, Food and Agricultural Code.

Section 502. Standard Methods for Examination of Dairy Products.

Except as otherwise herein provided, the collection of samples of milk or cream for bacteriological examination, when taken for determining value or upon which basis of payment is made, must be secured under the supervision of a technician licensed by the Department of Food and Agriculture as provided for in Section 351627 of The Food and Agricultural Code. The taking of samples and the technique followed in determining the bacterial content of milk or cream, when taken for determining value or upon which basis for payment is made, must be in a manner described in the current edition of the "Standard Methods for the Examination of Dairy Products", 17th Edition, of the American Public Health Association. Such samples must be representative and must be taken from the container from which the milk is sold, at least once each half month.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921, 35161, 35162, 35163, 35164, 35166, 35167 and 35168, Food and Agricultural Code.

Section 503. Duplicate Records.

All persons holding a technician's license shall make duplicate records of the result of each test, the original to be made with indelible pencil or ink and the duplicate to be made by the use of carbon paper.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921, 35161, 35162, 35163, 35164, 35166, 35167 and 35168, Food and Agricultural Code.

Section 504. Forms for Bacteria Count Bacteriological Record Sheets.

- (a) The forms on which bacteria counts are kept shall be of satisfactory paper stock of suitable size, and providing space for necessary information. Such forms shall be approved in writing by the California Department of Food and Agriculture.
- (b) Each sheet shall be authenticated by the signature of the licensed technician and marked with the date upon which the tests were made. All bacteria test records shall be permanently identified with the name or number of the concern for whom the tests are made. The name and address of the testing laboratory shall appear on the bacteria test record sheet.

- (c) The original bacteriological record sheet shall be delivered to the management of the concern for whom the tests are made immediately upon completion of the bacterial examination.
- (d) All persons holding a technician's license shall make duplicate records of the result of each test, the original to be made with indelible ink.
- (d) (e) The duplicate bacteriological record sheets shall be available at the laboratory in hard copy for no less than 30 days, in addition to any back up copies of the data. After 30 days the records may be archived to any type of removable storage media where they are to be kept for a minimum of two years.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921, 35161, 35162, 35163, 35164, 35166, 35167 and 35168, Food and Agricultural Code.

Section 505. Changing Records.

Whenever a change in the records, while still in the possession of the licensed technician, is necessary, the original entry on the records shall be marked out with a single stroke of the pencil or pen without defacing the figure and the correction noted immediately adjacent to the original entry. The change shall be identified by the initials of the technician, which are to be written on the record immediately adjacent to the correction. Whenever for any cause a change in the records is necessary after the duplicate sheet has been deposited in the official sealed box maintained for this purpose, a record of such change shall be made and deposited in the official sealed box and this sheet authenticated by the signature of the licensed technician. When necessary changes are made on the original test sheet, such changes shall be made only by the licensed technician.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921, 35161, 35162, 35163, 35164, 35166, 35167 and 35168, Food and Agricultural Code.

Section 506. Bacteriological Record Sheets.

(a) The original bacteriological record sheet shall be delivered to the management of the concern for whom the tests are made immediately upon completion of the bacterial examination.

(b) The duplicate bacteriological record sheets shall be deposited immediately in an official box provided by the person for whom the bacteriological determinations are made, such box shall be made in accordance with specifications obtained from the Director of Food and Agriculture, and be kept in the test room or other place approved by an authorized representative of said Department of Food and Agriculture at all times. The same official box may be used for both milk fat test record sheets and bacteriological examination record sheets.

Section 508. Butter Grader's License.

In accordance with Section 35135 of the Food and Agricultural Code, applicants for butter grader's license must take an examination given by the Department of Food and Agriculture and must secure a grade of at least 70 percent in each part of an oral, written, and demonstration examination, before a license will be issued.

2) Repeal section 512.3 and 527; Amend sections 509, 510, 511, 512, 512.1, 512.2, 514, 515, 516, 517 and 525; Add sections 513 and 513.5 of Article 14 of Chapter 1, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Article 14. Official and Approved Testing Methods and Protocols

Section 509. Official and Approved Testing Methods.

This article shall govern the assurance of the accuracy and precision of the official final action methods and the other acceptable methods of comparable accuracy when used to determine the components of milk, <u>bulk milk</u>, <u>products of milk</u>, or <u>products resembling milk products</u>, and cream when such component determinations are required as a basis of <u>for payment</u>, or to meet a legal compositional requirement of <u>Part 2 (commencing with section 35601)</u> and <u>Part 3 (commencing with section 36601)</u>, of

<u>Division 15 of the Food and Agriculture Code</u>. The official final action methods and procedures of analyses used by laboratories operated by the Department of Food and Agriculture shall be deemed to be official for all regulatory purposes.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921, 34231 and 34261.5, Food and Agricultural Code.

Section 510. Official Final Action Methods of Analysis.

Any testing for milk components that requires one or more of the tests described in <u>Ssection 32921</u> of the Food and Agricultural Code to be used as an official final action determination, shall, except where variations are approved in writing by the <u>director Department</u>, be conducted by procedures and equipment outlined in the <u>latest 18th</u> edition of the Official Methods of Analysis of the Association of Official Analytical Chemists International, which is incorporated by reference.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921 and 34261.5, Food and Agricultural Code.

Section 511. Approved Testing Methods of Comparable Accuracy.

- (a) Each of the testing methods listed in this section is approved for use as an acceptable method of analysis for the determination of the components of milk and, cream, when such component determinations are required as a basis of payment bulk milk, products of milk, or products resembling milk products and shall be conducted by procedures and equipment outlined in the 18th edition of the Official Methods of Analysis of the Association of Official Analytical Chemists International, which is incorporated by reference.
 - (a) Babcock method for fat in milk and cream.
- (b) Roese Gottlieb method utilizing Mojonnier equipment for fat in milk and cream, total milk solids, and milk solids not fat.
- (c) Gravimetric procedure utilizing a microwave oven for total milk solids and milk solids not fat in milk and cream.

- (d) Gravimetric procedure utilizing a forced draft oven for total milk solids and milk solids not fat.
 - (e) Light transmission method for milk fat in raw milk.
- (f) Infra Red light transmission method for milk fat, milk protein, milk lactose, and total milk solids not fat in raw milk.
 - (g) Dye binding methods for milk protein.
 - (h) The Lactometric procedures for total milk solids and milk solids not fat, by the Quevenne method or the 102^e Fahrenheit U.S.D.A. method.
 - (1) Fat in Raw Milk, Babcock Method, AOAC Official Method 989.04
 - (2) Fat in Milk, Modified Mojonnier Ether Extraction Method, AOAC Official Method 989.05
 - (3) Fat in Cream, Babcock Method, AOAC Official Method 995.18
 - (4) Fat in Cream, Mojonnier Ether Extraction Method, AOAC Official Method 995.19.
 - (5) Fat in Cream, Roese-Gottlieb Method, AOAC Official Method 920.111.
 - (6) Solids
 - (Total) in Milk, By Direct Forced Air Oven Drying, AOAC Official Method 990.20.
 - (7) Solids-Not-Fat in Milk, AOAC Official Method 990.21.
 - (8) Fat, Lactose, Protein, and Solids in Milk, Mid-Infrared Spectroscopic Method, AOAC Official Method 972.16.
 - (9) Lactose in Milk, Polarimetric Method, AOAC Official Method 896.01.
 - (10) Lactose in Milk, Enzymatic Method, AOAC Official Method 984.15.
 - (11) Protein in Milk, Dye Binding Method I, AOAC Official Method 967.12.
 - (12) Nitrogen (Total) in Milk, Kjeldahl Method, AOAC Official Method 991.20.
 - (13) Nonprotein Nitrogen in Whole Milk, Kjeldahl method, AOAC Official Method 991.21.
 - (14) TCA Precipitated Protein Nitrogen Content of Milk, Kjeldahl Method, AOAC Official Method 991.22.
 - (15) Protein Nitrogen Content of Milk, Indirect Kjeldahl Method, AOAC Official Method 991.23

(i) (b) Each of the approved testing methods of comparable accuracy utilized in the testing of milk for payment purposes shall comply with the required levels of accuracy and precision outlined in Section 512.2(d) (e) of this article.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921, 34202, 34231 and 34261.5, Food and Agricultural Code.

Section 512. Testing Procedures and Equipment.

- (a) Except where approved in writing by the <u>director Department</u>, licensees making tests by the approved testing methods stated in <u>Ssection 511</u>, shall use equipment and follow the methods and procedures outlined in the <u>latest 18th</u> edition of the Official Methods of Analysis of the Association of Official Analytical Chemists <u>International (AOAC)</u>, which is incorporated by reference. In the absence of prescribed equipment, methods, and procedures in AOAC, or when the <u>director Department</u> has documented evidence that a deviation from AOAC procedures and equipment will provide testing results that are at least as accurate and precise as results obtained under AOAC procedures, he <u>the Department</u> may give written authorization to use other testing methods and deviations.
- (b) For laboratories that test raw milk for payment by infrared (IR) instrumentation, pursuant to section 511(a)(5) of this article, the procedures and precalibration checks outlined in section 15.121 of "Standard Methods for the Examination of Dairy Products", 17th edition, which is incorporated by reference, must be followed. A letter requesting approval of an individual instrument for IR payment testing must be submitted to the Department, along with results of the pre-calibration checks and results of a minimum of 4 consecutive sets of IR calibration samples. All mean differences and standard deviations shall meet the established tolerances, and individual differences shall meet the tolerances with a 95% confidence interval. All data will be reviewed and approved by the Department prior to the instrument being approved for payment testing.
- (b) (c) When the Babcock method is utilized for the testing of milk and cream for fat content, the readings between lines of demarcation shall be extrapolated and reported to the nearest five one hundredths of one percent (0.05%) or less for milk and the nearest twenty-five one hundredths of one percent (0.25%) or less for cream.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921 and 34261.5, Food and Agricultural Code.

Section 512.1. Testing Equipment.

- (a) All calibrated measuring devices, weights, scales, or other analytical equipment used by any licensed tester or licensed technician, with any of the official final action testing methods or with other acceptable testing methods of comparable accuracy that are approved for use, shall be accurate, precise, in good working condition, and otherwise meet the director 's Departmental approval.
- (b) With the exception of pipets, all measuring glassware used for payment purposes shall be examined by the director and if it is found to be accurate, each piece shall have a legible and indelible distinguishing mark placed upon it by the department. All measuring glassware used for basis for payment testing shall meet or exceed the specifications for such apparatus outlined in the 18th edition of the Official Methods of Analysis of the Association of Official Analytical Chemists International, which is incorporated by reference.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921 and 34261.5, Food and Agricultural Code.

Section 512.2. Character of Work and Tolerances.

- (a) "Accuracy" means the degree of agreement of individual measurements with an accepted reference value. The accepted reference value shall be the analytical result made by the Department of Food and Agriculture. "Precision" means the degree of mutual agreement among individual measurements made under prescribed-like conditions.
- (b) After having given written notice to notifying the management of any milk distributor, milk processor, dairy association, or commercial testing laboratory, the director Department may obtain samples of any milk or cream previously tested by a licensed tester for the payment of any milk or cream or component of milk or cream—and which samples will be tested in the department's dairy laboratory to determine the accuracy and precision of the licensed tester's work. These samples may be tested in

the Department's dairy chemistry laboratory to determine the accuracy of the licensed tester's work. The Department may request that the licensed tester retest the sample at the original testing facility by the same method as the sample was originally run, to determine the precision of the tester's work.

(c) Persons making milk component tests by any approved or final action testing methods for payment purposes shall be able to demonstrate a capability to reproduce their own original tests and be able to produce work comparable to official final action tests from duplicate samples tested by the Department's of Food and Agriculture Ddairy chemistry Llaboratory within the limits outlined in subsection (d) (e) of this section.

(d)

ACCURACY AND PRECISION OF MILK TESTS

BETWEEN RETESTS AND/OR OFFICIAL LABORATORY TESTS

		Accuracy			Precision		
		Mean Difference			Maximum Difference		
		5-8	9-16 17-34		Standard	Between Original	
		Tests	Tests	Tests	Deviation	Test and Retest	
	Component Component	+	+	+		+	
(1)	% Milk Fat	0.04	0.03	0.02	0.05	0.10	
(2)	% Total Solids	0.07	0.05	0.04	0.08	0.16	
(3)	% Solids Not Fat	0.07	0.05	0.04	0.08	0.16	
(4)	% Protein	0.05	0.04	0.03	0.06	0.12	

(d) Where analysis of milk components for payment purposes are made by infrared instrumentation, the Department will provide calibration samples to laboratories at a frequency established by mutual agreement but no less than that recommended in the instruction manual of the manufacturer of the instrument. The laboratory must demonstrate that they meet the required precision and accuracy as outlined in subsection (e) of this section.

(e)

Example 1 CHECKING ACCURACY AND PRECISION WITH STATE DAIRY LABORATORY REFERENCE TESTS Percent of Milk Fat in Milk

		•••		
	Industry Lab	State Lab	Difference	Difference
	Any Method	AOAC Method	$(X_1 - X_2) \times 100$	x100, Squared
Sample Number	X 4	X 2	Đ	D^2
1	3.26	3.31	-5	25
2	3.46	3.49	-3	9
3	3.34	3.36	-2	4
4	3.56	3.61	-5	25
5	3.52	3.62	-10	100

6	4.15	4 .18	_3	9
7	4 .66	4 .68	-2	4
8	<u>4.84</u>	<u>4.91</u>	<u>-7</u>	<u>49</u>
SUM			-37	225

Mean Difference (Ď) as Accuracy

 $\check{D} = \xi D / n = -37 / 8 = -4.6 / 100 = -0.046$

Standard Devistion (S) as precision

$$S = \sqrt{\frac{ED^2 - (\check{D} \times D)}{225 - (-4.6 \times -37)}} = 2.8 \rightarrow 2.8 / 100 = 0.028$$

The industry lab meets the required precision (0.05), but does not meet the required accuracy (±0.04).

٤ = Sum

Ď = Mean of Difference

D² = Square of Difference

S = Standard Deviation

N = Number of Sample

→ = Transformation

Example 2
CHECKING ACCURACY AND PRECISION WITH STATE DAIRY
LABORATORY REFERENCE TESTS

	rcent of Solids No Industry Lab	State Lab	Difference	Difference
	Any Method	AOAC Method	$(X_4 - X_2) \times 100$	x100, Squared
Sample Number	X 4	X_2	Đ	D^2
1	8.62	8.40	22	484
2	8.44	8.41	3	9
3	8.51	8.50	4	4
4	8.64	8.62	2	4
5	8.66	8.69	-3	9
6	9.17	9.23	-6	36
7	9.17	9.45	-28	784
8	<u>8.91</u>	<u>8.92</u>	<u>-1</u>	<u> </u>
SUM			-10	1,328

Mean Difference as Accuracy

$$\dot{D} = \frac{\xi}{D} / n = -10 / 8 = -1.25 / 100 = -0.013$$

The industry lab meets the required accuracy (±0.07), but does not meet the required precision (0.08).

ACCURACY AND PRECISION OF MILK TESTS BETWEEN RETESTS AND/OR OFFICIAL LABORATORY TESTS

	Acci	<u>uracy</u>	_	<u>Precision</u>	
	<u>Mean</u> Difference		- <u>Standard</u> <u>Deviation</u> <u>of the</u> - Difference	Maximum Difference between original test & retest	
	<u>5-8</u>	<u>9-16</u>	<u> (SDD)</u>		
<u>Component</u>	<u>Tests</u>	<u>Tests</u>	<u>(300)</u>		
	<u>±</u>	<u>±</u>			
<u>% Milk Fat</u>	<u>0.04</u>	0.03	<u>0.05</u>	<u>0.06</u>	
% Total Solids	0.07	<u>0.05</u>	<u>0.08</u>	<u>0.12</u>	
% Solids Not Fat	0.07	0.05	<u>0.08</u>	<u>0.12</u>	
<u>% Protein</u>	0.05	0.04	<u>0.06</u>	<u>0.05</u>	
<u>% Lactose</u>	0.05	0.04	0.06	<u>0.07</u>	

- (f) When a retest on an individual samples of milk exceeds the maximum difference allowed in subsection (d) (e) of this section, the retest shall be used, unless the difference is so great between the original test and the retest as to warrant discard of the sample results and application of the averaging procedures of Section 525(h). sample is deemed to be unsuitable for testing due to oiling off, churning, water in the sample, or other sample anomaly, in which case the application of the averaging procedures in section 525(f) of this article, shall be used. A test on an individual sample of milk that exceeds the previous test average (minimum of 4 samples to arrive at previous test average) by more than 0.2 % for any component will automatically trigger a retest.
- (g) When a retest on an individual sample of milk does not exceed the maximum difference allowed in subsection (e) of this section the original test must be used as the basis for payment, and the original test will be reported on the original test sheet, with an explanation of the retest.
- (g) (h) When a retest on a sample of cream amounts to seventy-five hundredths of one percent (0.75%) or greater, the retest shall be used, unless the difference is so great between the original test and the retest as to warrant discard of the sample results and sample is deemed to be unsuitable for testing due to oiling off, churning, water in the sample, or other sample anomaly, in which case the application of the averaging procedures in Section 525(h) of this article shall be used.

- (h) (i) All active and relief licensed testers will be checked for the accuracy and precision their work The Department may check the accuracy and precision of licensed testers' work by unannounced inspections. The Department will review the work of licensed testers will be reviewed whenever a complaint is made regarding the accuracy and precision of their work. A licensed tester not regularly engaged in testing for payment purposes fro a period of 60 days is considered to be inactive. They will not be checked while inactive, but must notify a representative of the Bureau of Milk and Dairy Foods Control on resuming testing activities. A relief licensed tester relieves licensed testers during vacations, holidays, sick leave, or other emergency periods.
- (i) Any person engaging or employing a licensed tester to conduct tests on milk or cream received, purchased, or sold on its milk component content must at the time determine if such tester has been inactive. If so, the employer must notify the Regional Office of the Bureau of Milk and Dairy Foods Control.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921 and 34261.5, Food and Agricultural Code.

Section 512.3. Licensing.

Testers may be licensed to perform each of the official final action methods of analysis listed in Section 32921 of the Food and Agricultural Code.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921 and 34261.5, Food and Agricultural Code.

Section 513. Babcock, Gerber and Mojonnier Tests Infrared Instrumentation.

The Department approves of the use of mid-infrared instruments that rapidly determine the percentages of the fat, protein, lactose and solids content of milk as outlined in the 17th Edition of Standard Methods for the Examination of Dairy Products, which is incorporated by reference, including all precalibration testing requirements and routine instrument performance checks, when such findings form the basis for payment for raw milk.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 32921, 34202, 34231, 34261.5, 35784, 38181, 38191-38213, Food and Agricultural Code.

Section 513.5 Operation of Infrared Instruments.

- (a) The following shall govern the determination of milk components by Infrared (IR) instrumentation:
- (1) Persons testing raw milk by means of IR instrumentation shall hold a tester's license for IR and work under the supervision of personnel also licensed for IR testing, and responsible for all aspects of component payment testing at the facility.
- (2) Each day the IR instrument is used, a check (pilot) sample warmed according to section 15.121 of the 17th Edition of Standard Methods for the Examination of Dairy Products, which is incorporated by reference, with the temperature verified and recorded prior to testing, shall be analyzed at start-up and once every hour thereafter. The pilot sample can be a commercially prepared pilot sample, UHT whole milk, pasteurized whole milk, or raw milk or similar matrix. The pilot sample shall be handled, prepared, and tested in the same manner as producer payment samples. The pilot sample component values will be determined by averaging several instrument readings, after having cleaned and zeroed the instrument. The average instrument readings for each component will be used as the baseline to compare the daily start-up and hourly pilot samples. The results shall be recorded in the permanent log book, in accordance with subsection (a)(5). The component values on the pilot samples shall be less than or equal to 0.04% of the original base line values. If any component value on a pilot sample exceeds the original base line value by more than 0.04%, the instrument shall be cleaned and zeroed, and a fresh pilot sample shall be run. If any of the pilot sample components still deviate from the baseline values by more than 0.04% the instrument will be considered to be malfunctioning, and all payment samples analyzed since the last acceptable pilot sample shall have their results reported using the averaging procedures outlined in section 525(f) of this article. In the event of instrument malfunction further testing must be done by alternate official final action methods, or acceptable methods of comparable accuracy. If the laboratory cannot perform the

above methods, payment samples must be sent to another payment laboratory for analysis. The laboratory management shall submit a letter to the Department's Milk and Dairy Food Safety Branch identifying the alternate official final action methods and/or alternate laboratory that shall be used to analyze payment samples in the event of instrument malfunction, and update the letter as circumstances change.

- (3) Samples of raw milk which are high in acidity, coagulated, or churned may not be tested by IR.
- (4) If at any time the tester licensed to make milk component determinations by IR has reason to believe the results obtained are biased or inaccurate, all further testing must be done by alternate official final action methods listed in Food and Agricultural Code section 32921, or by acceptable methods of comparable accuracy, or the samples shall be tested by another payment laboratory until the bias is eliminated.
- (5) The recommendations provided in the Instruction Manual of the manufacturer for calibration, sample preparation, operation, routine maintenance, daily instrument checks, and cleaning shall be followed, unless otherwise instructed in writing by a representative of the Department. A permanent log book shall be maintained that records the results of all pilot samples, as well as information pertaining to any adjustments made to the instrument (i.e. maintenance, calibration changes, daily instrument checks, and any other work done on the instrument). The log book shall be available for review by the Department upon request.
- (6) The volume of the test portion shall be sufficient to make an original test and a retest. This volume may vary by instrument depending on the individual instrument volume uptake settings.
- (7) The power input to the IR instrument shall be standardized by a constant voltage regulator.
- (8) The IR instrument must be operated in an air-conditioned room where the temperature does not exceed 80°F.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Section 32921 and 34261.5, Food and Agricultural Code.

Section 514. Samples, Sampling and Weighing.

- (a) Bulk mMilk and cream must be thoroughly mixed and stirred before samples are taken in accordance with the 17th Edition of Standard Methods for the Examination of Dairy Products, which is incorporated by reference, for at least five minutes before sampling, or longer as may be required to obtain a representative sample throughout the tank. Containers of a size larger than a 10-gallon milk can Bulk milk tanks from which samples are taken must be equipped with power-driven mechanical devices which will thoroughly mix the milk or cream prior to sample collection to be sampled and shall be kept operating at all times while milk or cream is being weighed and sampled. Such mechanical devices shall be of a type and installed in a manner approved by the Director of Food and Agriculture Department. Samples shall be representative of the fat content of the product sampled. and in cases of composite samples shall be proportionate in amount to the amount of product from which the sample is taken, and in no part of the composite sample shall be spilled or lost while transferring it to the sample bottle. When any style of tube is used to secure composite samples and the lot of product to be sampled is in containers or cans of different sizes and diameters, different tubes with diameters in proportion to the diameters of the cans or containers must be used. Sampling tubes and dippers that are badly dented, or leak, must not be used. Cylindrical shaped dippers, only, shall be used when samples are secured with dippers. The sampling devices shall be rinsed in the product to be sampled before any part of the product is transferred to the sample bottle. Sample bottles shall be filled away from the farm tank opening so that no milk is spilled back into the farm tank. Sample bottles shall be filled no more than three quarters full to permit proper mixing of the sample at the laboratory. With reference to the last sentence in Section 34233 of the Food and Agricultural Code, further provision is hereby made permitting the use of time composite samples of cream from patrons where regular deliveries of cream contain three pounds or less of milk fat in each delivery.
- (b) Time composite samples of milk and cream, when used as a basis for payment for the milk fat contained in the product, must not represent a period of more than eight days.
- (c) (b) Samples shall be marked for identity with the date and the producer's name or patron number in a manner that will not erase, and in case an identification

number is discontinued, the same number may not be reapplied to another patron for a period of at least two months.

- (d) (c) Weights must be read and recorded to the nearest half-pound graduation on the scales for cream, and the nearest one-pound graduation for milk or weights taken or measurements made in a manner and to an accuracy acceptable to the Sealer of Weights and Measures.
- (e) (d) At the time samples are being taken, licensee will be held responsible for the operation of operating the mechanical agitators in a manner that will assure a representative sample, and for securing a correct weight or measurement.
- (f) All active and relief licensed testers must keep their current licenses displayed at all time in the test room, or laboratory where they are employed.

NOTE: Authority cited: Sections 407 and 34261.5, Food and Agricultural Code. Reference: Sections 32731, 32734, 34201, 34231, 34265, 34301, 35163, Food and Agricultural Code.

Section 515. Cream Sample Bottles.

- (a) Cream samples for testing shall be held in wide mouthed bottles of at least two-ounce capacity and must contain at least two fluid ounces of sample when they are received in the test room to be tested, and when taken on truck routes sample bottles must be filled to the top to prevent churning in transit, closed with a tight-fitting rubber stopper securely fastened to the bottle, when the patron's name or number appears thereon, or otherwise hermetically sealed in a manner approved in writing by an authorized representative of the Department of Food and Agriculture of the State of California.
- (b) Milk samples for testing may be held in a container of the same style specified for cream, or in milk bottles closed with a tightly fitted, nonabsorbent milk bottle cap or in a manner acceptable to the Director of Food and Agriculture.

Milk and cream samples to be tested for payment purposes shall be collected and held in single use plastic vials or bottles made of plastics that are manufactured from known chemical content, which does not contain materials that migrate into the food which may adversely affect the composition or bacteriological quality of the product.

NOTE: Authority cited: Section 407, Food and Agricultural Code. Reference: Sections 34351, 35166, Food and Agricultural Code.

Section 516. Milk Preservatives.

- (a) For preserving milk samples for milk fat determination, a solid preservative completely soluble in the sample may be added in sufficient amount to preserve the milk, but must not exceed 0.1 percent of the total weight of the sample; or liquid preservative may be added in sufficient amount to preserve the sample, but must not exceed two drops of preservative per fluid ounce of milk. Any preservative used shall be of a type approved by the Director for the testing method or methods utilized by the testing laboratory.
- (b) For preserving cream samples for milk fat determination a solid preservative completely soluble in the sample may be added if necessary, but must not exceed 0.3 percent of the total weight of the sample; or liquid preservative may be added not to exceed two drops of preservative per fluid ounce of cream.
- (c) Time composite samples must always be well mixed whenever an addition is made to any such sample in order to diffuse the preservative throughout the sample and to thoroughly mix any cream which may have adhered to the walls of the sample bottle, but not violently enough to cause churning, wet the stopper or allow any milk to escape from the sample bottle.

For preserving milk samples in the laboratory for the determination of milk components, bronopol (0.02 - 0.06 percent by weight of the sample), bronopol with a yeast and mold inhibitor (0.02 - 0.06 percent by weight of the sample), or potassium dichromate (0.1 percent maximum by weight of the sample) may be used. A request for approval for the use of other preservatives not specified in this section, must be submitted in writing to the Department prior to use. Any milk sample tested within 3 days after the sample is collected need not be preserved.

NOTE: Authority cited: Sections 407 and 34231, Food and Agricultural Code. Reference: Section 34231(b), Food and Agricultural Code.

Section 517. Storage and Testing of Samples.

- (a) The management of each facility that tests milk or cream for basis for payment shall designate one licensed tester to be the responsible party (designee) for ensuring that the samples are received, stored, handled, prepared, tested, and recorded as outlined in sections 499, 509, 510, 511, 512, 512.1, 512.2, 513, 513.5, 515, 516, 517, and 525 of Title 3 of the California Code of Regulations, and ensure that all personnel who test samples for payment are licensed testers. The designee shall also be responsible for ensuring that the daily calibration checks are performed and recorded properly, and that the instrument is maintained according to the manufacturer's suggested guidelines. Management shall, within at least 24 hours, notify the Department by telephone or electronic mail when there is a personnel change with regard to the designee, and make certain that at all times there is a trained backup person available to take over the designee's role.
- (a) (b) Each person purchasing, receiving, or selling milk or cream on the basis of milk fat or milk fat and fluid skim—milk components shall provide a refrigerator maintained at a temperature of 40° F or below between 0° and 4.4°C. in which licensed weighers, samplers and testers shall keep all samples taken or maintained during sampling and holding periods. All such samples shall be kept in a locked, secure place in the refrigerator which shall be constructed and maintained in a manner acceptable to the Director Department. Said secure area shall remain locked except while samples are being placed therein or removed therefrom by licensed weighers, samplers, and testers, Keys and lock combinations for said secured area shall only be possessed by or made known to licensed testers, weighers, and samplers who are required to have access to the secured area as part of their duties. Written procedures shall be in place to ensure the security of the samples at all times. A copy of the written procedures shall be submitted to the Department at the time the laboratory requests approval for payment testing, whenever procedures or methods are changed, or when requested by the Department.
- (b) Any milk sample tested within 3 days after the sample is taken need not be preserved; all other samples shall be preserved at the time the sample is taken. Market milk samples may be accumulated for a maximum of 4 days at the ranch, a storage

depot, or plant before delivery to the laboratory for analysis, which must be commenced within the first working day after the samples are delivered to the laboratory.

Nothing in this section precludes composite sampling of manufacturing milk or cream or market milk under the provisions of Food and Agricultural Code Section 34231(f).

(c) A licensed tester shall retain in his custody unmodified sSamples of all milk and cream tested by him at a payment laboratory shall be maintained for a period of at least 72 hours after testing. if they are daily or lot samples, and for a period of at least 120 hours if they are time composite samples. He The laboratory designee shall be personally responsible for their safekeeping.

NOTE: Authority cited: Sections 407 and 34231, Food and Agricultural Code. Reference: Sections 32921, 34231, 34261, 34261.5, 34262, 34263, 34264 and 34265, Food and Agricultural Code.

Section 525. Keeping Records of Tests.

- (a) All licensed milk and cream testers shall make duplicate records of the results of such tests, the original to be made with Indelible pencil or ink and the duplicate to be made by the use of carbon paper, and all tests shall be permanently identified with a patron name or number. All duplicate test record sheets and duplicate retest sheets must be made perfectly legible with the carbon paper used. All tests and retests of milk and cream must be entered directly on the official sheets.
- (a) All milk and cream test record sheets shall be permanently identified with the name or number of the concern for whom the tests are made. Daily test records must be available at the laboratory in hard copy for no less than 30 days, in addition to any back up copies of the data. After 30 days the records may be archived to any type of removable storage media where they are to be kept for a minimum of two years.
- (b) The forms on which test records are kept shall be approved in writing by the Department of Food and Agriculture.
- (c) (b) Each <u>test record</u> sheet shall be authenticated by the full signature of the licensed tester, marked with the complete date on which the tests were made, and the time covered by the tests date the sample was taken. The name and address of the

person, firm, company, or association purchasing, receiving, or selling the product that has been tested shall appear on the test record sheets. The name and address of the testing laboratory shall appear on the test record sheet. If an infrared instrument is used, the serial number of the instrument used to test the samples shall appear on each test record sheet.

(d) (c) Whenever a change in the records, while still in possession of the tester, is necessary by the reason of accident or failure to properly record the test, or when a retest is made, and the retest is sufficiently different from the first test, as specified in section 512.2 (e), the original entry on the records shall be marked out with a single stroke of the pencil or pen, without obliterating the figures, and the correction or retest noted immediately adjacent to the original entry. The change shall be identified by the initials of the tester, which are to be written on the test_record sheet_immediately adjacent to the correction. Whenever, for any such cause, a change in the records is necessary, after the duplicate test record sheet has been deposited in the official sealed box maintained for this purpose, a record of such change shall be made by the licensed tester on a retest sheet. Any changes or corrections occasioned by these retests are to be made on the original test record sheet, by the licensed tester only, and then this retest sheet deposited in the official sealed test record sheet box. Any grade or color of paper as large as six by eight inches will serve for a retest sheet and it is not compulsory that the retest sheets be made in duplicate. If the employer requires the licensed tester to make retest sheets in duplicate and the licensed tester does not make the occasioned changes or corrections on the original test record sheet in the office, the original retest sheet must be permanently fastened to the original test record sheet. in the office to which it belongs, and the duplicate retest sheet deposited in the official sealed test record sheet box. The name and address of the person, firm, company, or association purchasing, receiving, or selling the product retested must be entered on all retest sheets. Two dates must appear on all retest sheets--one showing the date the retest was made and the other showing the date that the milk or cream was first tested. All retest sheets must be made with indelible pencil or ink and be signed with the full name of the tester. All retests must be accompanied by the patron's name or number in order to determined to whom the sample retested belonged.

- (e) When a retest on a sample of milk shows a variation not exceeding one tenth of 1 per cent the original test must be used as the basis for payment. If the variation exceeds one tenth of 1 per cent the retest must be used.
- (f) (d) The original test record sheets shall be delivered to the management of the concern for whom the tests are made immediately upon completion of the tests on the day's samples.
- (g) Upon completion of the tests on the day's samples the duplicate test record sheets shall be deposited immediately in an official sealed box made in accordance with the specifications obtained from the Department of Food And Agriculture of the State of California, such official test record box to be kept in the test room at all times, or in an appropriate and secure place convenient to the test room, and duplicate test record sheets must not be left out of the sealed test record sheet box over night.
- (h) (e) When sample bottles leak or they are lost, or the contents are partly spilled, or the bottles are broken or cracked, or for any other reason the sample is not representative, notation of occurrence must be made on the test record sheet by the licensed tester. In such cases an averaged test must be given to the patron, based on the average of the four immediately preceding tests if the sample was a milk sample. In the case of a sample of cream, the averaged amount of fat shall be based on the average of four deliveries of cream from the same patron, immediately preceding the day for which the fat is averaged.
- (i) (f) Weights or measurements must not be changed without approval of the director Department, except where obvious errors have been made by the licensed sampler and weigher. An average weight or measurement based on the four immediately preceding recorded weights, whenever available, shall be used if the actual correct weight cannot be determined.
- (j) (g) Explanations as to averaged tests on milk and averaged amounts of fat or cream, and averages in weights or measurements must appear on both the original and duplicate patron statements. All such changes must be identified with the name or initials of the plant manager or the person responsible for these records.

NOTE: Authority cited: Sections 407 and 34231, Food and Agricultural Code. Reference: Section 34231(b), Food and Agricultural Code.

Section 527. Observation of Laws, Rules and Regulations.

A licensed tester shall at all times thoroughly understand and comply with all laws, Rules, and Regulations governing the testing of milk or cream purchased, received, or sold on the basis of the amount of milk fat contained therein by any method or process, and must secure accurate results.

3) Repeal Article 14.5 and sections 536, 537, 538, 539, 540 and 541 of Chapter 1, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Article 14.5. Nonfat Milk Solids Testing and Reporting

Section. 536. Operations and Methods.

This article shall govern the operations and methods of determination of the nonfat milk solids of milk where such milk is purchased, received or sold on the basis of its nonfat milk solids content.

Section 537. Samples and Records.

The provisions of Administrative Code Sections 514, 515 (b), 517, 525, 526 (a), (c), (d) and (e) relating to the fat testing of milk shall apply to the testing of nonfat milk solids of milk.

Section 538. Preserving and Compositing of Samples.

- (a) For preserving milk samples for nonfat milk solids determinations only liquid preservations acceptable to the director may be added. The preservative must not exceed two drops (0.1 ml.) per fluid ounce of milk.
- (b) Time composite samples shall be well mixed whenever an addition is made to any such sample so as to diffuse the preservative throughout the sample and to thoroughly mix any cream which may adhere to the walls of the sample bottle, but not violently enough to cause churning, wet the stopper or allow milk to escape from the sample bottle.

Section 539. Test Room Equipment for Nonfat Milk Solids Testing.

- (a) Any scales or balances used in weighing milk for analysis of the nonfat milk solids must be accurate and have a sensitivity of not more than 0.1 milligram.
- (b) When the gravimetric procedure is used, the scales or balances must be fixed in position or set on an even, solid and level support and while in use must be free from vibrations and drafts.
- (c) When the gravimetric procedure is used, a desiccator shall be used for cooling the sample after drying and before weighing.
- (d) All equipment used shall be cleaned after each using and shall be rendered free from any foreign matter.
- (e) Any instrument used for the determination of nonfat milk solids of milk by the lactometric method shall be accurate within 0.5 lactometer degrees and such scale division shall represent no more than 0.5 lactometer degrees or its equivalent.
- (f) Any instrument used for the determination of nonfat milk solids of milk by the lactometric method shall be checked for accuracy by the Department of Agriculture at a cost of not less than \$1 each. After checking and acceptance as being within tolerance, such instrument shall bear a legible and indelible distinguishing mark indicating official approval.
- (g) Where the lactometric method is used, the chamber for the reception of the milk and lactometer shall have a diameter at least one-half inch greater than the maximum diameter of the lactometer. If a device other than a lactometer is used, the container shall be of adequate size and shape to permit accurate performance of the test used.

Section 540. Averaging of Tests.

Where analysis of nonfat milk solids of milk are made on a lot or lots of milk by a licensed nonfat milk solids tester representing the buyer and a licensed nonfat milk solids tester representing the seller, in the absence of a mutually acceptable arbitration, any differences will be resolved by using the findings of the nonfat milk solids tester using the gravimetric procedure. When both testers use the same procedure, an arithmetic average of the two tests will form the basis for resolution.

Section 541. Samples.

- (a) When a sample of milk is taken for analysis of nonfat milk solids determination, the sample shall be sufficient for at least three (3) analyses by the procedure used.
- (b) Samples of milk may be used for both fat and nonfat milk solids determinations provided the sample is adequate in volume.
- (c) For nonfat milk solids determinations, the fat test used must represent the same lot or lots of milk as the milk for which the nonfat milk solids determination is used. Any fat test used must be an analysis and not a mathematical calculation.

4) Repeal Article 14.6 and sections 543 and 544 of Chapter 1, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Article 14.6. Testing of Raw Milk for Butterfat by Light Transmission

Section 543. Milko-Tester.

Licensed testers using the Milko-Tester, an electronic transistorized apparatus utilizing light transmission for determining the butterfat content of raw milk on which payment is based, shall follow explicitly the current instructions for calibration, operation, maintenance, and cleaning of the equipment issued by the manufacturer, unless otherwise instructed in writing by an authorized representative of the California Department of Food and Agriculture. In no case shall the method of calibration deviate from the current instructions of the Association of Official Analytical Chemists.

Section 544. Milko-Tester Operation.

The following shall govern the operation of the Milko-Tester:

- (a) The latest edition of the manufacturer's operation manual shall be available at all times in conjunction with the instrument.
- (b) The minimum sample for use by the Milko-Tester for fat determinations shall be five ounces for both fresh and preserved samples.

- (c) Where the Milko-Tester is used, supplemental Babcock or Mojonnier equipment must be provided. The tester utilizing the Milko-Tester must be licensed for both the Milko-Tester and the Babcock or Mojonnier methods of analyses.
- (d) The Milko-Tester must be equipped with a constant voltage transformer.

 (e) It is the responsibility of the license tester to determine that the Milko-Tester is operating correctly. If at any time he believes the results obtained are biased, all further testing must be done by the Babcock or Mojonnier method until the bias has been eliminated.
- (f) Samples used for calibration shall be prepared in the same manner as samples upon which producer payments are to be based. They shall be retained for the same time and under the same conditions as for official samples used for basis of payment. Samples used for calibration shall include samples in the butterfat ranges of 3-4 percent and 6-7 percent.
- (g) When any sample differs in butterfat content by greater than 2.0 percentage points from the sample preceding it through the instrument, there shall be an immediate retest and the second test shall be the one recorded. On all retesting of samples, the retest shall be the test used.
- (h) All calibration results and check tests for initial calibration and all tests for checking the accuracy of calibration shall be recorded in a permanent record book.
- (i) "Official test" means milk sampled and tested for its butterfat content by means of the Babcock test or any equally accurate and efficient test approved by the Director of Food and Agriculture.
- (j) Any instrument shall read to the second decimal place and shall report findings to the second decimal place.
- (k) During the use of the Milko-Tester each day, a sample of milk of known percentage of fat shall be tested with the Milko-Tester after every 30 tests and the results shall be recorded on the permanent test record. If at any time there is variation from the original test exceeding 0.04, the Milko-Tester must be rinsed thoroughly with versene solution and the machine checked for zero setting in order to get agreement on the test of the standard. At least three standard checks must then be run and if the average variation is in excess of 0.06, the Milko-Tester must be recalibrated. If after the three standard checks are run and the instrument is recalibrated, then all samples run

after the last check sample must be retested. The results of the rechecks will become official.

(I) Potassium dichromate, not more than one tenth of one percent by weight of sample of market milk, must be used if a preservative is added to the milk sample.

5) Repeal Article 14.7 and sections 546 and 547 of Chapter 1, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Article 14.7. Testing of Raw Milk for Butterfat and Other Milk Constituents by Infrared Light Transmission

Section 546. Infrared Milk Analyzer (IRMA).

The Director of Food and Agriculture approves in principle the use of the Infra Red Milk Analyzer (IRMA) as a means of determining the percentage of butterfat, protein, and lactose when such findings form the basis of payment for raw milk. The Infra Red Milk Analyzer (IRMA) is basically a double beam infra red grating spectrometer which compares the absorption of a sample of milk with that of pure water at three key wavelengths in the infra red region of the spectrum. At these three wavelengths, absorption occurs which is specific to fat, protein, and lactose respectively. The optical density at each wavelength is measured and automatically multiplied by calibration factors to give a direct reading in percentage components. The Director of Food and Agriculture approves the concept of the conversion of lactose, protein, and a predetermined constant to reflect the percentage of solids-not-fat. The predetermined constant shall be on the basis of the average of a series not less than 100 total solids examinations of raw milk by any method recognized by the Association of Official Analytical Chemists. The constant shall be the total solids less the percentage of butterfat, lactose, and protein on the same samples after the instrument has been standardized for the determination of these constituents. The frequency of the constant determinations shall be at the discretion of the Director. Approval of the installation and operation of the Infra Red Milk Analyzer (IRMA) shall be on an individual basis and shall follow the constant determination taken from samples in the geographical area of the dairies likely to be involved.

Section 547. Operation of IRMA.

The following shall govern the determination of milk constituents and solids notfat by the Infra Red Milk Analyzer (IRMA)

- (a) Persons testing raw milk by means of IRMA instrumentation shall be licensed for IRMA and work under the supervision of personnel also licensed for IRMA
- (b) In the event of instrument malfunction or failure to meet reproducibility standards which shall not exceed + 0.1% for butterfat and + 0.1% for solids not fat, supplemental approved testing facilities with licensed testers must be provided for testing milk for milk fat and solids-not-fat.
- (c) Corrosive sublimate or potassium dichromate at the maximum of 0.1% by weight of the sample may be used as a preservative for raw milk samples tested by IRMA.
- (d) Samples of raw milk which are high in acidity, coagulated, or churned may not be tested by IRMA.
- (e) On retests of the same sample where the difference exceeds 0.1% for butterfat or solids not fat by IRMA determinations, the retest shall be considered the official test.
- (f) If at any time the tester licensed to make fat and solids not fat determinations by IRMA has reason to believe the results obtained are biased or inaccurate, all further testing must be done by supplemental equipment until the bias is eliminated.
- (g) Once IRMA is standardized to the satisfaction of the Director, the standardization dials for butterfat, protein, and lactose shall be sealed by the Director. If the seals are broken by any person other than a representative of the Bureau of Milk and Dairy Foods Control, the licensee shall notify the Bureau before testing is resumed. However, the standardization dials for butterfat, protein, and lactose need not be sealed, provided numerical readings of the control adjustments are recorded in ink in a bound book with the date, time, reason for the changes, and the signature of the person making the changes.
- (h) The recommendations provided in the Instruction Manual of the manufacturer for calibration, operation, maintenance, and cleaning shall be followed, unless otherwise instructed in writing by a representative of the Bureau of Milk and Dairy Foods Control.

- (i) Composite samples in excess of 2 ounces in volume may be reduced in volume by a licensed tester. This will facilitate the operation of the test provided the volume of the test portion is sufficient in volume to make a retest and to hold volume for two tests by a representative of the Bureau of Milk and Dairy Foods Control.
- (j) The power input to IRMA shall be standardized by a constant voltage regulator.
- (k) The IRMA must be operated in an air-conditioned room where the temperature does not exceed 80oF.
- (I) In the event that IRMA does not have an automatic printer attachment, the licensed tester shall manually record the analyses from the digital read out.
 - (m) The completed tape when used shall reflect:
 - (1) The name and address of the laboratory.
 - (2) The signature of the licensed tester.
 - (3) The date of analyses and the date of the period covered by the sample(s).
 - (4) The percentage of butterfat.
 - (5) The percentage of protein and lactose, respectively.
- (6) The percentage of protein, lactose, and the factor may be converted to solidsnot fat on the tape; however, the solids not fat may be calculated from the protein and lactose on the tape plus the factor at any time prior to calculation of solids-not-fat for payment.
- (n) During the use of IRMA each day, a prepared sample or a sample of raw milk of known percentage of butterfat, protein, and lactose shall be tested after each 30 samples. The results shall be recorded in a permanent test record book. If the instrument findings for any constituent deviates from the percentage of the constituent in the check sample by more than ±; 0.04%, the instrument balance shall be adjusted. If any or all constituents deviate from the percentage in the check sample by more than ±; 0.1%, all samples from the last check sample shall be retested and the findings of the retest used as the official sample.

6) Repeal section 550; Amend sections 551, 552, 553 and 554 of Article 14.8 of Chapter 1, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Article 14.8 Third Party Testing

Section 550. Purpose.

This article interprets Section 34231 and related sections of the Food and Agricultural Code.

NOTE: Authority cited: Sections 407 and 34231, Food and Agricultural Code.

Section 551. Definitions.

For the purposes of this Article, the term "third party" means a commercial laboratory or any laboratory approved by the <u>Director Department</u> having no vested interest in the laboratory findings of specific analyses.

NOTE: Authority cited: Sections 407 and 34231, Food and Agricultural Code.

Reference: Sections 34201, 34231, Food and Agricultural Code.

Section 552. Interpretation of Section 34231(e) Interplant Bulk Sales of Commingled Milk.

- (a) Exemption provided in Section 34231(e) shall apply to interplant bulk sales of milk by a nonprofit cooperative association to a distributor.
- (b) (a) For bulk sales of commingled milk from members' ranches to a distributor when such deliveries are made by a non-profit cooperative association or its agent, the non-profit cooperative association shall be deemed a single producer subject to the provisions of Section 34231(b) and (c) of the Food and Agricultural Code.
- (c) (b) For direct sales from its individual members' ranches when the milk is picked up by a distributor or his agent, the non-profit cooperative members shall be considered an individual producers subject to the provisions of Section 34231(b) and (c).

NOTE: Authority cited: Sections 407 and 34231, Food and Agricultural Code.

Reference: Sections 34231 and 34301, Food and Agricultural Code.

Section 553. Procedures for Assignment Designation.

In the absence of mutual agreement, as provided for in subsection (c) of Section 34231, in making assignment of third party testing, the Director will be guided by, but not limited to the following:

- (a) The Director will not provide the physical facilities for testing but may, on request of a laboratory, provide a qualified state employee to test in facilities provided by producers or processors, producers and processors, and commercial laboratories.
- (b) The Director will approve a contract between producers and a distributor and an Approved Milk Inspection Service maintained by a county health department only under the following conditions:
- (1) When no commercial testing facilities are available within reasonable proximity to the plants or collection points for producer samples.
- (2) When the physical facilities are approved by the Director and laboratory personnel are licensed to perform all required analyses.
- (3) When sufficient licensed personnel are provided for relief and emergency analyses.
- (c) In a geographical area, assignment preference will be given to commercial laboratories, and where no commercial laboratories are available, to an industry laboratory using state personnel for the performance of such analyses.
- (d) (a) In a geographical area, a \underline{A} designation of a laboratory or laboratories by the <u>Director Department</u> will be based upon a combination of the following criteria:
 - (1) Accuracy of analytical procedure.
- (2) Capability of laboratory or laboratories in terms of time and frequency of analyses.
 - (3) Capability of laboratory or laboratories in terms of logistic requirements.
 - (4) (3) Lowest cost of service to be performed.
- (e) In making specific assignment or assignments in a geographical area, preference will be given but not limited to the laboratory or laboratories utilizing the most accurate analytical procedures.

"Most accurate analytical procedures" are construed to be:

- (1) IRMA--Infra Red Milk Analyzer (fat and solids-not-fat),
- (2) Mojonnier (fat and solids-not-fat), and

(3) Milko-tester (milk fat) in combination with gravimetric solids-not-fat analysis.

By mutual agreement, producers and buyers may choose to use any other analytical procedure approved by the Director.

When two laboratories in a geographical area use different analytical procedures of equal accuracy, preference will be given to the laboratory utilizing the method which can be performed at the lesser unit cost of analysis.

- (f) Where analyses of fat and other milk constituents are made by instrumentation, the Director will provide for the submission of calibration and maintenance samples to laboratories at a frequency established by mutual agreement but no less than that recommended in the instruction manual of the manufacturer of the instrument.
- (g) Prior to assignment of a third party testing facility by the Director, a representative of the Bureau of Milk and Dairy Foods Control will schedule a meeting with representatives of the producers, the processor, and the third party to be assigned. The purpose of the meeting will be to discuss procedures relating to the contract, and will include:
- (1) Provisions for joint payment for the cost of testing by processor and producers.
- (2) Provisions for operation and supervision of analytical methods used for testing.
- (3) Emergency provisions for equipment breakdown or other unusual circumstances.
 - (4) Reporting of analytical results by third party.

The meeting called by a representative of the Bureau of Milk and Dairy Foods Control is to assist all parties in their deliberations. The Director reserves the right to make the assignment to a third party on his own motion.

- (h) (b) Whenever there is a substantial change in circumstances on which assignment designation was predicated, the Director Department shall be advised by the parties; in such an event, the Director Department will determine whether a change in assignment designation shall be made.
- (i) Where services are provided by the Director under contract, cost will be computed according to provisions of current law.

(j) (c) When, as a result of prescribed written application under provision of Ssection 34231(c) of the Food and Agricultural Code, the Director assigns Department designates third party testing, such assignment designation shall be deemed operative for the distributor and for all producers shipping to the milk plant affected.

NOTE: Authority cited: Section 407 and 34231, Food and Agricultural Code. Reference: Sections 34921, 34233 and 34301, Food and Agricultural Code.

Section 554. Resolution of Test Variations.

In the absence of mutual agreement or—assignment designation provided for in subsection (c) of Section 34231 of the Food and Agricultural Code, analyses of milk fat and non-fat milk solids of milk made on a lot or lots of milk by a licensed tester(s) representing the seller and a licensed tester(s) representing the buyer, any differences in findings will be resolved by using the findings of the laboratory utilizing the most accurate analytical procedure. When both testers use the same procedure, an average of the two tests will form the basis for resolution of the differences. If one or both samples are available, additional analyses shall be made.

NOTE: Authority cited: Sections 407 and 34231, Food and Agricultural Code.

Reference: Section 34301, Food and Agricultural Code.

7) Amend section 604.1 of Article 21 of Chapter 1, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Section 604.1 Analysis Confirmation of Compliance Testing on Finished Fluid Milk Products.

When raw market milk for pasteurization is purchased on the basis of the percentage of milk fat and solids not fat, and the analyses are made by instrumentation, the control agency, whether the Department of Food and Agriculture or an Approved Milk Inspection Service using conventional analytical methods for analysis of packaged milk to determine compliance with legal standards, shall, before any action for failure to comply with standards, have analyses confirmed by either an approved electronic, Mojonnier, or gravimetric test.

- (a) When analyses of finished fluid milk products are made by mid-infrared instrumentation, the Department shall, before any action for failure to comply with the standards of composition established by sections 35784, 38181, 38191 and 38211 of the Food and Agricultural Code, have analyses confirmed by the methods listed in this section. The AOAC Official Method numbers indicated below refer to methods outlined in the 18th Edition of the Official Methods of Analysis of the Association of Official Analytical Chemists International, which is incorporated by reference.
- (1) Fat in Milk, Modified Mojonnier Ether Extraction, AOAC Official Method 989.05
- (2) Solids (Total) in Milk, By Direct Forced Air Oven Drying, AOAC Official Method 990.20
 - (3) Solids-Not-Fat in Milk, AOAC Official Method 990.21
- (b) To determine compliance with legal standards of composition, the final analytical results (lab value) from confirmation methods listed in this section shall have an expanded uncertainty value applied as follows:
- (1) Fat results on milk, reduced fat milk, lowfat milk and nonfat milk will have an expanded uncertainty value of \pm 0.03 percent fat applied to the lab value.
- (2) Total Milk Solids (TS) results on milk will have an expanded uncertainty value of \pm 0.07 percent solids applied to the lab value.
- (3) Solids Not Fat (SNF) results on milk, reduced fat milk, lowfat milk and nonfat milk, will have an expanded uncertainty value of ± 0.07 percent solids applied to the lab value.
- (c) Written complaints sent to the Department objecting to a final analytical result used to determine compliance with legal standards of composition shall be kept on file with a copy of that final analytical result for two years.

NOTE: Authority cited: Sections 407, 34231 and 34261.5, Food and Agricultural Code. Reference: Sections 34202, 34261, 34262, 34263, 34264, 34265, 34301, Food and Agricultural Code.

(end)